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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/069,995	06/17/2002	Roger John Butlin	056291-5077	5772

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EXAMINER	
BERNHARDT, EMILY B	
ART UNIT	PAPER NUMBER
1624	

DATE MAILED: 07/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/069,995	BUTLIN ET AL.	
	Examiner	Art Unit	
	Emily Bernhardt	1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 April 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,4-7,9,10 and 16-21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4-7,9,10 and 16-21* is/are rejected.

7)☒ Claim(s) *8* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Claim 18 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claim newly presented is directed to treating all forms of ischaemias, eg. cerebral, retinal,etc. Specification describes treating myocardial ischaemia which was originally claimed.

Claims 1,2,4-7,9-10,16-21 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The rejections of the previous action are maintained for the following reasons:

1. With regard to the scope of compounds still claimed, it is not seen how applicants' amendment to main claim 1 overcomes the rejection as applicants do not point to any representative examples encompassing any heterocyclic species much less the array of choices permited at R3 . Describing the invention as broadly

as it is claimed does not necesaarily enable one how to make and use the invention. Note the following quote taken from In re Cauvallito which was cited in Surrey at p.205,left column: "The mere statement of an inventive concept, however, is not a sufficient basis for claiming it. Sufficient information must be given to enable those skilled in the art to practice the invention.".

2. Other than the uses originally presented in claims 14 and 15 the uses now present in claims 18-20 are not enabled based on solely on activity as PDH inhibitors. Note that claim 18 if limited to treating myocardial ischaemia would no longer be rejected. However for remaining uses there remains no competent evidence of record that such are art-recognized for treatment based on elevating PDH activity. Applicants point to a reference cited in specification for Alzheimer's but it appears to be speculative and the reference is not seen in the record nor is it readily available to the examiner. Nor have any other references on this page been provided to support the remaining uses. Aicher and remaining references relied on by the examiner are more recent than any of the articles cited in the specification and yet make no such assertions. Applicants in exchange for a 17-20 year monopoly must evidence that the utility is definite and in currently available form and not merely for further investigation or research. Note Brenner v. Manson 148

USPQ 689 and the more recent decision Genentech vs. Novo Nordisk 42 USPQ 2d 1001 which echoed the same concern.

The 102 (b) rejection is overcome by deletion of D as C(O) and OC(O). However the following rejection still applys.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1,2,4-7,10 and 16-18 are rejected under 35 U.S.C. 102(a) as being anticipated by Aicher for reasons of record and citing Timmons as supplementary evidence of what Aicher teaches. Aicher remains a competent reference in view of the lack of compliance with 35 USC 112, par.one as discussed above. New claim 17 which is limited to treating peripheral vascular disease is also rejected herein . While Aicher does not expressly mention this disorder, Aicher describes other uses for PDH inhibitors that involve reduced oxidation of pyruvate and lactate. See p.237, left column. Timmons expressly teaches peripheral vascular disease as being involved in a similar mechanism to ischaemia which results in lowered levels of pyruvate oxidation. Thus following the teachings of Aicher one would be administering an instant drug that inhibits PDH and thus increases pyruvate oxidation for which the uses rejected have been correlated. Note extrinsic evidence is permitted to be considered in anticipations for explaining or evidencing

what the meaning of the main reference would have meant to those skilled in the art. Note for example, Ciba-Geigy v. Alza 37 USPQ 2d 1337.

Claim 8 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Emily Bernhardt whose telephone number is (571) 272-0664.

If attempts to reach the examiner by phone are unsuccessful, the supervisor for AU 1624, Dr. Mukund Shah, can be reached at (571)272-0674.

The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

E Bernhardt

EMILY BERNHARDT

PRIMARY EXAMINER

Group 1600